37

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,298	ALLEN, ANN DE WEES	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-9 and 11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-9 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 5-9 and 11-15 are presented for examination.

Applicant's Amendment, Declaration and Terminal Disclaimer filed January 30, 2006 have each been received and entered into the present application. Accordingly, the specification at pages 2, 4 and 7 has been amended, claims 1-3, 5-6, 8-9, 11-13 and 15 have been amended and claims 4 and 10 have been cancelled.

In view of the foregoing amendments and remarks made herein, the objection to the oath/declaration; the objections to the claims and the specification; and the rejection of the claims 2, 4, 8, 10, and 15 under 35 U.S.C. 112, second paragraph; as set forth at pages 2-5 of the previous Office Action dated July 28, 2005 have each been hereby **withdrawn**.

In view of the acceptable nature of the Terminal Disclaimer filed January 30, 2006, the rejection of claims 1-15 under the judicially created doctrine of obviousness-type double patenting as set forth at pages 15-17 of the previous Office Action dated July 28, 2005, has been hereby **withdrawn**.

Objection to the Declaration (New Ground of Objection)

Applicant's submission of a newly executed declaration for inventor Ann de Wees Allen has been noted and placed of record in the file.

However, Applicant has incorrectly identified one of the U.S. Patent Applications to which the present application claims priority. Applicant cites to U.S. Patent Application No. 08/215,556, filed March 22, 1994, which should properly read "08/215,667" as stated in the cross-reference to related applications in the present disclosure.

A new oath or declaration in compliance with 37 C.F.R. 1.67(a) identifying this application by serial number and filing date is required. Please reference MPEP §§602.01 and 602.02.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I Claim 1 remains rejected under 35 U.S.C. 102(b) as being anticipated by Winitz (U.S. Patent No. 3,697,287; 1972), already of record, for the reasons of record set forth at pages 6-7 of the previous Office Action dated July 28, 2005, of which said reasons are herein incorporated by reference.

Applicant submits that Winitz discloses compositions with a plethora of amino acids, which is in direct contrast to the present invention, which is only arginine with optional leucine, isoleucine and valine. Applicant further submits that it is not a certainty that the composition of Winitz has sufficient amounts of any amino acid to stimulate muscle growth.

Applicant's amendments and remarks have each been carefully considered in their entirety, but fail to be persuasive.

Applicant's claim 1 presently states:

"A composition for stimulating muscle growth, wherein said composition has an amino acid component that consists essentially of a muscle growth stimulating effective amount of L-arginine and, optionally, one or more amino acids selected from the group consisting of L-leucine, L-isoleucine, and L-valine and wherein said composition further comprises any one or combination of ingredients selected from the group consisting of chromium; choline, sodium borate; and vitamin B5."

In response to Applicant's assertion that the presently claimed composition distinguishes over the prior art of Winitz because it is directed only to arginine with optional leucine, isoleucine and valine where Winitz is directed to a plethora of amino acids, the Examiner points out that the present claims are not limited only to a composition of arginine, but clearly provide for embodiments wherein any one or more amino acids selected from L-leucine, L-isoleucine or L-valine is present. Such embodiments are clearly anticipated by Winitz, who teaches composition comprising L-arginine, L-leucine, L-valine or L-isoleucine, in combination with d-calcium pantothenate and choline bitartrate (see Tables I and II of Winitz, for example). Applicant's attention is directed thereto the cited portions of Winitz.

While Applicant argues that there is no certainty that the composition of Winitz has sufficient amounts of any amino acids to stimulate muscle growth, it is noted that the present claims do not expressly recite quantitative amounts of amino acids that must be present in order to meet the limitations of the claim. Absent such specific quantities, there is no reason to doubt that the amount of amino acids taught by Winitz would not also be capable of stimulating muscle growth, absent factual evidence to the contrary, because Winitz meets each and every physical or structural limitation of the claim.

It is further noted that the present rejection does not rely on the principle of inherency as noted in Applicant's remarks at page 8 of the Amendment. In response to Applicant's argument that Winitz fails to show certain features of Applicant's invention, namely the muscle-stimulating effective amounts, it is noted that the features upon which Applicant relies (i.e., the express quantities of the active agents necessary to induce muscle-growth stimulation) are not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Please reference *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For these reasons, and those already made of record at pages 6-7 of the previous Office Action dated July 28, 2005, rejection of claim 1 remains proper and is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I Claims 1-3 and 5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Winitz (U.S. Patent No. 3,697,287; 1972) in view of Durst (U.S. Patent No. 3,434,843; 1969) and Millman (U.S. Patent No. 4,871,550; 1989), each already of record, for the reasons of record

set forth at pages 7-9 of the previous Office Action dated July 28, 2005, of which said reasons are herein incorporated by reference.

Cancellation of claim 4 renders the present rejection under 35 U.S.C. 103(a) **moot** as applied to such a claim.

Applicant states that the cited references do not suggest or provide the expectation of success and states that hindsight reconstruction cannot support a rejection under 35 U.S.C. 103. Applicant submits that the cited references are not directed to the problem addressed by the presently claimed invention (i.e., stimulation of muscle growth in a palatable, efficient and metabolically favorable way).

Applicant's amendments and remarks have each been carefully considered in their entirety, but fail to be persuasive.

Applicant is reminded that present claims 1-3 and 5 are drawn to a composition comprising, in its broadest embodiment, L-arginine and one or more amino acids selected from L-leucine, L-isoleucine or L-valine, and may further comprise any one or combination of chromium, choline, sodium borate or vitamin B5 for the stimulation of muscle growth. In other words, Applicant intends to use the present composition for the stimulation of muscle growth.

As taught by the MPEP at §2111.02[R-2]:

"*If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction*...During examination, statements in the preamble reciting the purpose or intended

use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art...If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim." (emphasis added)

In accordance with the teachings of the MPEP at §2111.02[R-2], a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. It is clear from the present case that the cited references do fully and intrinsically set forth each and every physical and structural limitation of the presently claimed composition. Thus, following the direction of the MPEP at §2111.02[R-2], the intended use of the composition, i.e., for stimulating muscle growth, is not considered a limitation of the presently claimed composition. Absent factual evidence to the contrary, the prior art structure is capable of performing the intended use and, thus, meets the claims.

Furthermore, while Applicant again argues that the cited references do not address the particular amounts of the presently claimed active agents, Applicant's claims are not drawn to particular concentrations of the active agents and, thus, do not patentably distinguish over the teachings of the cited references. Even if the claims did recite express concentrations of the active agents, Applicant has failed to make a showing of the criticality of such concentrations. Absent such evidence, the particular concentrations of the present claims are not seen to be inconsistent with those that would have been determined by the skilled artisan easily through route experimentation and optimization. Please reference MPEP §2144.05.

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment of obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Insofar as the skilled artisan would have been motivated to administer chromium or sodium borate with the composition disclosed by Winitz, it is clear from the citation of Durst and Millman that both compounds were well known in the art as essential food nutrients and, thus, would have potentiated the nutritive enhancement provided by the nutritional composition of Winitz. Such a conclusion was based solely on the knowledge available to one of ordinary skill in the art and did not rely on Applicant's specification. Despite the fact that the motivation to combine the references as stated in the previous Office Action is not identical to Applicant's reason for combining, the fact that Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant's argument that Durst or Millman do not remedy the shortcomings of Winitz clearly does not address the combined teachings as set forth in the previous Office Action. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's

claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references. *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); *In re Keller* 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Moreover, it is noted that rejections under 35 U.S.C. 103(a) are based on combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one of ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

For these reasons and those already made of record at pages 7-9 of the previous Office Action dated July 28, 2005, rejection of claims 1-3 and 5 remains proper and is **maintained**.

II Claims 6-9 and 11-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rudman et al. ("Growth Hormone Treatment of Frailty in Men Over 60", *New England Journal of Medicine*, 1990), Dudrick et al. (U.S. Patent No. 5,026,721; 1991) and Boynton et al. (U.S. Patent No. 5,087,624; Issued 1992; Priority to 1987), each already of record, for the reasons of record set forth at pages 10-15 of the previous Office Action dated July 28, 2005, of which said reasons are herein incorporated by reference.

Cancellation of claim 10 renders the present rejection under 35 U.S.C. 103(a) **moot** as

applied to such a claim.

Applicant states that the claims now presented exclude the presence of lysine via the use of the transitional phrase "consisting essentially of". Applicant submits that Dudrick et al. and Boynton et al. do not cure the deficiencies of Rudman et al. and, in fact, Dudrick et al. teaches a supplement comprising lysine, which teaches away from the current invention. Applicant further submits that Rudman et al. does not disclose the combined use of leucine, isoleucine and valine and that the reference teaches that the arginine supplement must be accompanied by a high dose of choline, where the present claims use an especially small dose of choline.

Applicant's amendments and remarks have each been carefully considered in their entirety, but fail to be persuasive.

First, regarding the use of the transitional phrase "consisting essentially of", the MPEP states at §2111.03, "The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention...For the purposes of searching for and applying prior art under 35 U.S.C. §102 and §103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."

Applicant has failed to definitively point out the basic and novel characteristics of the invention. However, taken in its broadest, reasonable interpretation, the basic and novel characteristic of the presently claimed invention must necessarily lie in the fact that the composition must retain efficacy in stimulating muscle growth.

If the composition must retain efficacy in stimulating muscle growth, in order to preserve

the basic and novel characteristics of the invention, then the very fact that Applicant has claimed a composition "consists essentially of L-arginine and, optionally, one or more amino acids selected from the group consisting of L-leucine, L-isoleucine, and L-valine" (see present claim 6, for example) or "consists essentially of L-arginine and, optionally, one or more amino acids selected from the group consisting of L-leucine, L-isoleucine , and L-valine" (see present claim 12, for example) is necessarily met by the cited references. The inclusion of lysine does not alter the ability of the composition to either stimulate muscle growth or to stimulate an immune response. In fact, absent factual evidence to the contrary, Dudrick et al. teaches that the presence of lysine contributes to the overall improvement in muscle growth and sound nutrition, which the skilled artisan would have necessarily recognized as contributing to the enhancement of the overall health of the immune system and, thus, immune response. The fact that the presence of lysine actually preserves the function of the composition indicates that the present claims do not patentably exclude its presence as taught by Dudrick et al. because lysine does not appear to alter the efficacy of the composition for improving muscle growth or promoting sound nutrition, which would, in turn, affects the immune system.

Applicant's argument that Rudman et al. does not suggest the combined use of leucine, isoleucine or valine clearly does not address the combined teachings as set forth in the previous Office Action. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references. Please reference *In re Young*, 403 F.2d 754, 159

USPQ 725 (CCPA 1968); *In re Keller* 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Rudman et al. was not relied upon to teach the combination of leucine, isoleucine or valine. Dudrick et al. was relied upon to show that arginine, leucine, isoleucine and valine were known to improve muscle growth, strength and health via sound nutrition when administered. Thus, Applicant's assertion that Rudman et al. does not suggest the combination of leucine, isoleucine and valine is irrelevant to the present rejection because the reference was not relied upon for such a teaching. Applicant's attention is directed to Dudrick et al. for this teaching and the previous Office Action at pages 10-25 for why one of ordinary skill in the art would have been motivated to combine the individual teachings of both Rudman et al. and Dudrick et al.

Applicant asserts distinction between the presently claimed invention and the teachings of Rudman et al. by stating, "A further distinction between the subject invention and the teachings of Pearson et al. (Rudman et al.) is that the high doses of choline used by Pearson et al. causes users to have a very strong and offensive smell. Pearson et al. suggests that an arginine supplement must be accompanied by high doses of choline. For example, at page 6, Pearson et al. states that, "we recommend that, if you are taking arginine supplements, you also take one to three grams of choline..." However, in contrast, the current Applicant wishes to emphasize that the subject composition contains an especially small dose of choline, which, advantageously, eliminates the occurrence of body odor."

It is clear from Rudman et al. that he does not *require* the concomitant administration of 1-3 grams of choline with arginine. In fact, he states that, "we *recommend* that, if you are taking arginine supplements, you also take one to three grams of choline" (emphasis added). Such is a recommendation, not an absolute requirement. Regardless, Applicant argues a patentable

distinction over the amount of choline administered by Rudman et al., "a high dose of choline" (see page 12 of Applicant's remarks), and amount of choline in the presently claimed composition, "an especially small dose of choline" (see, again, page 12 of Applicant's remarks). However, Applicant's teaching of 700 mg or less of choline (see claims 9 and 11) is not seen to be significantly different that the 1 gm of choline taught by Rudman et al. such that the 1 gm of Rudman et al. would constitute a teaching away from the presently claimed invention. Thus, Applicant's assertion that the does of choline of Rudman et al. is markedly higher than that contemplated by Applicant is merely a subjective determination by counsel of what is considered a "high dose of choline" and what is considered an "especially small dose of choline" and fails to be a patentable distinction.

Moreover, it is noted that not all of the present claims recite a particular quantitative amount of choline (see present claims 6-7 and 12-15) and, thus, read on any amount of choline, including that expressly taught by Rudman et al. Thus, the argument that the amount of choline imparts patentably distinction to the present claims over the cited prior art is not a point well taken. Furthermore, absent any showing of the criticality of the amount of choline, and further, that such a critical amount was actually expressed throughout each of the claims, the amount of choline is not considered to impart patentably moment to the presently claimed invention.

For these reasons and those already made of record at pages 10-15 of the previous Office Action dated July 28, 2005, rejection of claims 6-9 and 11-15 remains proper and is **maintained**.

Conclusion

Rejection of claims 1-3, 5-9 and 11-15 remains proper and is **maintained**.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

March 24, 2006

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600